IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A**	**MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE PROPOSED TESTIMONY OF JULIE DROLET, M.D.

Plaintiffs submit this this Reply in further support of their Motion to Exclude the Proposed Testimony of Julie Drolet, M.D.

INTRODUCTION

Defendant proposes to offer into evidence Dr. Drolet's opinions regarding the safety and efficacy of the TVT-O and the Prolift+M. In their Motion, Plaintiffs demonstrated that Defendant has not met its burden to establish that Dr. Drolet's opinions are the product of a reliable methodology. Unsurprisingly, Defendant attempts to skirt this burden and instead argues that these fatal methodological deficiencies are not relevant to the inquiry regarding admissibility of expert testimony. Of course, the reliability of Dr. Drolet's methodology is the very essence of the inquiry here.

As shown below, and in Plaintiff's Motion, Dr. Drolet should be excluded from offering expert opinions in this case because: (1) she did not follow a reliable methodology in reviewing the relevant literature; (2) she completely failed to assess any of the contrary evidence, including contrary conclusions by the very evidence she relied upon; and, (3) her personal experience regarding these products is not a reliable basis for her opinions.

In their Response, Defendants admit many of these errors exist. For example, Defendant concedes in its briefing that:

(1) Dr. Drolet failed to disclose any reliable methodology regarding how she chose which studies to rely upon;

(2) Dr. Drolet failed to discuss the strengths and weaknesses of the studies she relied upon;

(3) Dr. Drolet failed to discuss *any* of the contrary evidence that contradicts her opinions;

(4) Dr. Drolet failed to reconcile inconsistent conclusions from evidence upon which she did rely;

(5) Dr. Drolet does not know how Prolift+M is different from Prolift; and,

(6) Dr. Drolet does not know whether there are any clinical benefits to using Prolift+M.

Dr. Drolet cannot simply ask the Court to accept her proposition that she relied upon the literature and her personal experience. She must show that she followed a reliable methodology. As discussed throughout the briefing, Dr. Drolet has not followed a reliable methodology. Accordingly, Dr. Drolet's testimony should be excluded.

ARGUMENT

Dr. Drolet has offered general causation opinions purportedly based on her review of the relevant literature and her personal experience. However, "reliance on literature and experience is not dispositive" because the Court must also ensure that the expert has "reliably applied" the methodology with the requisite level of intellectual rigor. *See Carlson v. Boston Scientific Corp.*, 2:13-cv-05475, 2015 WL 1931311, at *14 (S.D. W. Va. April 28, 2015). As discussed in this briefing and conceded by Defendants, Dr. Drolet did not reliably apply any methodology to the facts of the case.

I. DEFENDANT CONCEDES THAT DR. DROLET DID NOT MAKE A SYSTEMATIC REVIEW OF THE LITERATURE AND DID NOT DISCUSS ANY CONTRARY EVIDENCE.

Dr. Drolet purportedly reached *all* of her opinions in her report based on her review of the medical literature. In their Motion, Plaintiffs identified several fatal flaws showing Dr. Drolet failed to apply any reliable methodology in choosing the literature upon which she relied and instead cherry-picked studies that supported her opinions. In its Response, Defendant does not challenge this assertion. Instead, Defendant merely argues that an expert does not have to discuss "each and every" study. As discussed below, this misses the point – Dr. Drolet failed to identify how she chose the studies to review and failed to discuss *any* of the contrary evidence. In other words, she had no reliable methodology for choosing and reviewing the relevant scientific literature.

This Court has made it clear that cherry-picking is not a reliable methodology. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (explaining that an expert's opinion may be unreliable if he "fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape'"). Without some explanation for disagreement with contrary evidence, an expert's methodology is unreliable. *Id.* Here, the Defendant effectively concedes that Dr. Drolet failed to utilize any reliable methodology in choosing which studies to rely upon and which studies to discount. In essence, Defendant has conceded that Dr. Drolet selectively cites (or "cherry-picked") the studies she relied upon.

In its Response, Defendant argues that because Dr. Drolet cited to various studies in her nearly fifty page report, she has necessarily met the requirements under Rule 702 and *Daubert*. Of course, a reliable methodology is not established simply by the number of pages or citations in an expert's report. Here, Dr. Drolet did not follow any reliable methodology regarding how

she chose which studies to rely upon and did not disclose any independent analysis of the strengths or weaknesses of any of the studies.

Defendant also argues that the admitted lack of reliable methodology does not go to admissibility under *Daubert*. Defendant argues that an expert cannot address "each and every study." *Response* at 5. This straw argument misses the point – Dr. Drolet has not addressed or explained *any* of the contrary evidence, explained the strengths or weaknesses of the studies that do support her opinions, or provided any reliable methodology through which she selected the studies she upon which she relied. Nowhere in Defendant's briefing does it cite to even a single sentence from Dr. Drolet's report where she addresses a single piece of contrary evidence or explains why she discounted that study. This is simply because Dr. Drolet ignored all contrary evidence. Here, Dr. Drolet's unreliable methodology involves more than missing a "study or two," but rather she has employed an unreliable methodology that failed to address *any* contrary evidence that disagreed with her opinions.

Defendant erroneously argues that Dr. Drolet should be allowed to offer a narrative history of pelvic floor disorders and related treatments. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. June 4, 2013) (explaining that an expert "will not be permitted to exhaustively recount all of the facts of the case" and "will not be permitted to recount the entire history" of the product.). Plaintiffs agree that a concise overview would be helpful, *if Dr. Drolet was offering admissible expert testimony*. She is not.

Instead, Dr. Drolet merely recites the findings from various studies and provides no explanation regarding (1) how she chose these studies, (2) the strengths and weaknesses of the studies she chose, or (3) why she discounted other contrary evidence. This complete lack of methodology fails the *Daubert* inquiry. In its Response, Defendant has completely failed to

substantively address any of these methodological concerns. Accordingly, Dr. Drolet's opinions are not the product of a reliable methodology and must be excluded.

II. EVEN IF DR. DROLET EMPLOYED A RELIABLE METHODOLOGY TO REVIEW THE LITERATURE, HER OPINIONS REGARDING THE RISK BENEFIT PROFIILE OF THE PROLIFT+M ARE CONTRADICTED BY THE SCIENCE SHE CITES AND HER OWN EXPERIENCE.

Purportedly based on her personal experience and review of the relevant evidence, Dr. Drolet offers the opinions that the benefits outweigh the risks for the Prolift+M. In their Motion, Plaintiffs demonstrated that Dr. Drolet did not follow a reliable methodology specifically in reaching these opinions. Defendant argues that Plaintiffs' analysis is "nonsensical" because Dr. Drolet spent "more than 25 pages" explaining the medical conditions of POP and SUI and the related treatments. *Response* at 6. However, Dr. Drolet's extensive narrative history and selective citation to cherry-picked evidence are not reliable bases for expert testimony.

For example, in her report, Dr. Drolet makes the generalized statement that the benefits outweighed the risks of the Prolift+M. (Report at 27). She bases her opinion on statements from industry organizations such as the American College of Obstetricians and Gynecology (ACOG). *See Response* at 6. Yet, on the very next page of her report, Dr. Drolet quotes ACOG's conclusion that these products "should be reserved for **high risk individuals**." *Report* at 28 (emphasis added). In its brief, Defendant fails to address this contradiction and instead argues this continued lack of reliable methodology is not relevant to the admissibility inquiry.

Dr. Drolet's refusal to address contrary evidence, including this contrary statement from evidence she specifically cites to, further demonstrates her opinions are not the product of a reliable methodology. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014) (holding that inconsistent statements may "directly shed light on the unreliability of [an expert's] method"). Defendant concedes this evidence Dr. Drolet relies upon

does not actually support her generalized opinion regarding the risk benefit profile.

Dr. Drolet also asks the Court to find that she followed a reliable methodology, in part, because she relied upon her personal experience. However, in her deposition, it became apparent that Dr. Drolet is not actually familiar with this product. *Motion* at 4. The Prolift+M is an Ethicon device used to treat POP – a different device from the original Prolift device. Dr. Drolet stated in her report, "The Prolift+M was eventually developed by Ethicon in order to continue innovation…" *Report* at 7. However, Dr. Drolet testified she cannot even remember why she switched to the Prolift+M. She also testified that she is largely unfamiliar with the Prolift+M device. *Motion* at 4. Further, Dr. Drolet also testified she cannot remember whether the Proilft+M was easier to work with. Yet, Defendant argues that Dr. Drolet's opinions regarding Prolift+M based on her personal experience are sufficiently reliable to be presented to a jury.

Defendant's attempt to spin away Dr. Drolet's unfamiliarity with the Prolift+M also fails. Defendant argues that, "The Prolift+M and Prolift **may** have identical benefit-profiles and simultaneously the benefits of Prolift+M **can** still outweigh its risks." *Response* at 7 (emphasis added). These vague, uncertain, possibilities do not meet the scientific certainty that is necessary for expert testimony or the result of a reliable methodology.

Dr. Drolet's failure to address the contradictory conclusions from the very evidence she cites demonstrates she failed to follow a reliable methodology. Additionally, her unfamiliarity with the Prolift+M demonstrates that her personal experience with the product is an unreliable basis for her opinion. As such her specific opinions regarding the Prolift+M should be excluded.

III. DR. DROLET CANNOT TESTIFY REGARDING WHAT OTHER PHYSICIANS KNEW OR KNOW.

Dr. Drolet's report is replete with references to what "other" or "all" physicians knew or know. Unless Dr. Drolet is clairvoyant (something not disclosed on her CV), it is impermissible

for Dr. Drolet to testify to such rank speculation. Dr. Drolet has not undertaken any poll of the general medical community to reliably assess what other doctors knew about various topics and does not employ any reliable methodology to reach her speculative opinions.

Defendant argues that Dr. Drolet is not actually offering opinions regarding what "all physicians" knew or know. In doing so, Defendant argues that in her report, Dr. Drolet does not expressly use the phrase what 'is' known by 'all' physicians." *Response* at 7. Defendant's argument is pure semantics.

For example, Dr. Drolet, without reference to any data or documents, stated in her report that "[n]o matter the approach, **all gynecologists are** or should be **aware** of the surgical risks such as bleeding, infection, injury to nerves, organs and vessels, and post-operative risks…." *Report* at 9 (emphasis added). She also opined that, "[n]owadays **many gynecologists and urogynecologists believe** that the high recurrence rate may result from failure to address the descent of the uterus or vaginal vault concomitantly." *Report* at 8. Plaintiffs identify numerous other examples in their Motion. These opinions clearly are directed at what some unknown, unknowable physicians learned or know. Dr. Drolet should not be permitted to speculate regarding the state of knowledge of "many," "most," "all," or any other group of doctors.

Defendant next argues that Dr. Drolet "never attempts to impute knowledge to any **individual** surgeon…." *Response* at 7 (emphasis added). This is false. In her report, Dr. Drolet specifically offers opinions regarding the state of knowledge of a specific surgeon – Plaintiff's treating physician, Dr. Ehsani. Dr. Drolet states in her report, "[e]xperienced pelvic floor surgeons such as Dr. Ehsani, in her fellowship, would be aware of the frequency and severity of complications…." *Report* at 8. Again, this testimony is pure speculation.

Dr. Drolet is not a mind reader. She should not be permitted to testify about what other surgeons learned, knew or should know. She is not qualified to offer such opinions – in fact, no one is.

IV. DEFENDANT CONCEDES DR. DROLET WILL NOT OFFER OPINIONS AS TO INTENT

Defendant concedes that Dr. Drolet will not "opine regarding the intent of the medical device industry, Ethicon, or the FDA." *Response* at 9. However, Defendant then argues that the examples of Dr. Drolet's opinions regarding "intent" are not actually examples of her "attempting to opine on the intent or state of mind." *Id.* Plaintiffs disagree and request that the Court preclude Dr. Drolet from testifying as to intent of industry and the FDA, including these specific examples. These opinions regarding corporate intent, exceed what is necessary for a concise summary of the background facts. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611 (explaining that the expert "must draw on the facts only as necessary – and in as concise a manner as possible…").

V. DR. DROLET'S COMPLETE MISUNDERSTANDING OF THE FDA PROCESSES DEMONSTRATES SHE IS NOT QUALIFIED TO OPINE ON THE SAFETY OF PELVIC FLOOR DEVICES.

As one basis of her opinion that the TVT-O and Prolift+M are safe and effective, Dr. Drolet relies upon the FDA's clearance of those devices. In fact, Dr. Drolet testified that she believes that the clearance of a medical device for marketing under the FDA 510(k) is equivalent with the FDA making a determination that the device is safe and effective for its intended use. Of course, this is completely wrong. Defendant concedes as much in its briefing. However, this complete lack of understanding further undermines the reliability of her methodology.

Defendant concedes that Dr. Drolet is not qualified to testify about the FDA 510(k) process and concedes that she will not testify as to such matters. However, Dr. Drolet's testimony that FDA 510(k) clearance is equivalent to the FDA making a determination that device is safe and

effective, demonstrates the complete unreliability of her opinions. She simply assumes these products are safe, selectively cites to random articles that purportedly support her opinion, and even testifies that the FDA supports her opinions through its clearance of these products under the 510(k) process. Of course, the FDA has never made such a determination and this reliance on incorrect limited science and incorrect assumptions is insufficient support for her opinions.

VI. DR. DROLET HAS NOT FOLLOWED A RELIABLE METHODOLOGY TO REACH HER OPINIONS REGARDING THE ADEQUACY OF THE IFU.

Dr. Drolet offers the opinion that the IFU adequately warned of the potential risks associated with these products. As discussed below, this opinion is a legal conclusion and should be excluded. However, this opinion should also be excluded because she has not reached this opinion by following a reliable methodology as she has no understanding as to what standards govern the IFU.

Defendant concedes that Dr. Drolet does not know the FDA requirements for an IFU. Defendant further concedes Dr. Drolet does she not know the internal Ethicon standards governing what is required in an IFU. Dr. Drolet therefore assesses the adequacy of the IFU based on her, personal, subjective belief. Dr. Drolet's personal standard for the adequacy of labeling is unhelpful and irrelevant. Accordingly, Dr. Drolet's testimony should be excluded because she has not established that her opinions are the product of reliable methodology. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 611 (excluding testimony where despite "stellar qualifications as a urogynecologist," expert was "unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process").

VII. DR. DROLET'S LEGAL OPINIONS SHOULD BE EXCLUDED.

Dr. Drolet offers numerous conclusions regarding the legal issues here. Defendant implicitly acknowledges this is improper testimony for an expert, but erroneously argues that Dr.

Drolet's opinion that Ethicon "adequately warned" is not a legal conclusion. Of course, this is the ultimate issue for the jury to decide. As stated in Plaintiffs' Motion and conceded by Defendants, Dr. Drolet is not qualified to opine as to the regulatory requirements regarding warnings or Ethicon's own internal standards. These and other legal opinions should be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (holding that "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 629 (excluding testimony regarding legal conclusions such as manufacturer "failed to adequately disclose adverse risks associated with their products" and manufacturer "failed to warn on its label").

CONCLUSION

Dr. Drolet's few general causation opinions should be excluded for the reasons set forth above. The remainder of Dr. Drolet's general report, consisting of a narrative recitation of the history of prolapse and incontinence, should also be excluded because it would not help a jury understand any facts at issue in this litigation. For these reasons, the Court should grant Plaintiffs' Motion and exclude the proffered general causation expert testimony of Julie Drolet, M.D.

Respectfully submitted this 16th day of May, 2016.

/s/ Joseph J. Zonies
Joseph J. Zonies, Esq.
Reilly Pozner LLP
1900 Sixteenth Street, 17th Floor
Denver, Colorado 80202
(303) 893-6100
(303) 893-6110 fax
jzonies@rplaw.com

/s/ Thomas P. Cartmell

Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esq.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel.

/s/ Shea N. Shaver